K042981

MAR 1 0 2005

510(K) SUMMARY

HYPERQ™ SYSTEM

510(k) Number K_____

Applicant's Name:

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Contact Person:

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Date Prepared:

October 2004

Trade Name:

HyperQ™ System

Classification Name:

Monitor, Physiological, Patient (Without Arrhythmia Detection Or Alarms)

Establishment Registration No.:

Establishment registration form (Form FDA 2891) has been submitted but no registration number has been assigned yet.

Classification:

FDA has classified a Monitor, Physiological, Patient (Without Arrhythmia Detection Or Alarms) device as a class II device (product code MWI) and it is reviewed by the Cardiovascular Panel.

Predicate Device:

The HyperQ™ System is substantially equivalent to the PC ECG 1200 device (NORAV MEDICAL LTD.) cleared under K000404 in terms of intended use, indications for use, technological characteristics, performance and user interface.
The predicate device is a Class II medical device.

Performance Standards:

The HyperQ™ System complies with:
U.S. Federal Performance Standard set forth in 21 CFR 898 for electrode lead wires and Patient Cables.

In addition, the device complies with the voluntary recognized standards: IEC-601-1:1988 and amendments, IEC 60601-1-2:2001, IEC 60601-2-27:1994, IEC60601-2-25:1999 and amendment, IEC 60601-1-4:1996, EC53:1995, EC38:1998 and EC11:1991.

Intended Use / Indication for Use:

ECG

ECG is intended to disclose either normal condition or patterns of arrhythmia, myocardial ischemia, rate abnormalities, or features of prognostic value in the following cases:

- Patients with suspected cardiac abnormalities
- Populations of patients at an age or period in which a routine baseline evaluation of ECG characteristics is desired.

Stress Testing

Angina pectoris (chest pain) is a clinical syndrome resulting from myocardial ischemia, indicative of reduced blood supply to the cardiac muscle. The electrocardiogram may establish the diagnosis of ischemic heart disease if characteristic changes are present.

Stress testing is the most widely used method to decide whether this chest pain is related to myocardial ischemia, and thus to coronary artery disease. In stress testing, the contractile capability of the heart muscle is monitored via ECG

during patient exercise. Patients exercise by bicycle, treadmill, or other means, while the ECG is monitored continuously. Exercise loads are determined by predefined protocols. The ECG signals as well as the HF-QRS signals are recorded for the resting, exercise, and recovery phase portions of the exercise protocol. The changes in both ECG waveforms are compared to the resting ECG records. In the HyperQ™ stress test, changes in the high frequency of the mid QRS complex, calculated as root-mean-square (RMS) values, are compared to the resting values.

Most of the commercial stress test systems control the bicycle or treadmill automatically according to the requirements of the chosen protocol, although this is not essential.

ST segment monitoring is intended as an aid in the evaluation of myocardial ischemia in patients with known or suspected coronary artery disease. The ST segment algorithm has been tested for accuracy of the ST segment data, and a database is used as a tool for performance testing.

The significance of the ST segment changes **must** be determined by a physician.

HyperQ™

The HyperQ™ Software is intended to be used as an aid to stress ECG test by means of analysis of high frequency components present within the central portion of the QRS complex.

The significance of the HF-QRS changes **must** be determined by a physician.

Device Description:

The HyperQ™ System is a compact monitor for measuring, processing, storing, and displaying information derived from the following physiological measurements:

- Electrocardiogram (ECG). A twelve lead ECG is acquired and a waveform can be displayed real-time on the LCD screen, recorded or printed. The design of the ECG function is derived directly from the predicate device, the PC ECG 1200 device.
- Detection, analyzing and recording of the high frequency components of the QRS complex of standard ECG signals.

Substantial Equivalence:

There are no unique applications, indications, material or specifications presented herein. Evidence of equivalence has been demonstrated through:

- the HyperQ™ System has the same intended use as its predicate device, and;
- the HyperQ™ System has the same technological characteristics, (i.e., same materials, design, energy source, diagnosis algorithm and principle of operation as the predicate device, and;
- The HyperQ™ System includes a new off-line software module that does not raise new issues of safety or effectiveness based on previous pre-clinical and clinical studies and software validation.

Therefore, we believe that the HyperQ™ System is substantially equivalent to its predicate device cited above without raising new safety and/or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 0 2005

BSP Ltd.
c/o Arava HaCohen, RAC
A. Stein Regulatory Consulting
20 Hata'as St.
Kfar Saba 44425
ISRAEL

Re: K042981
Trade Name: HyperQ System
Regulation Number: 21 CFR 870.2300
Regulation Name: Physiological Patient Monitor (without arrhythmia detection or alarms)
Regulatory Class: Class II
Product Code: MWI
Dated: October 24, 2004
Received: October 29, 2004

Dear Mr. HaCohen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K042981
Device Name: HyperQ™ System
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Prescription Use ___√___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

B Krummen

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K042981